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Eileen Sheffield
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#20
Appeal Brief

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Johannes Reinmüller

Serial No. : 08/732,408

Filed : December 9, 1996

For : MEDICAL IMPLANTS MADE OF MOULDINGS

Group Art Unit : 3738

Examiner : J. Black

Commissioner of Patents
and Trademark
Washington, D.C. 20231

November 24, 1999

Sir:

APPEAL BRIEF UNDER 38 CFR § 1.192

S I R:

Applicants submit their Brief on Appeal. The Brief is submitted in triplicate together with the fee required by 37 CFR § 1.17(f), believed to be \$150.00. Authorization is given to charge deposit account no. 50-0624 if any additional fees are required.

(1) REAL PARTY IN INTEREST

The real party in interest is the inventor Johannes Reinmüller.

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(2) RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

(3) STATUS OF CLAIMS

Claims 1, 2 and 5-22 are pending as per the attached Appendix A.

(4) STATUS OF AMENDMENTS

All amendments have been entered.

(5) SUMMARY OF THE INVENTION

The invention relates to a moldable implant for the reconstruction of soft tissue made of a plurality of thin pliable structural elements made of a thin sheet of a physiologically compatible plastic having a thickness of 10-200 μm and a surface that is wettable by a fluid lubricant. The adjacent structural elements are displaceable one against the other, that is they can slide over one another.

(6) ISSUES

Did the Examiner err in finally rejecting claims 1, 2, 5, 11-14 and 19-22 as obvious over Shane?

Did the Examiner err in finally rejecting claims 6-10 and 15-17 as obvious over Shane in view of Wiese?

Did the Examiner err in finally rejecting claim 18 as obvious over Shane in view of Scarborough?

Applicant submits the Examiner did err.

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(7) GROUPING OF CLAIMS

All claims stand or fall together.

(8) ARGUMENT

The examiner has rejected the claims primarily in view of Shane, and it is believed that this is in error. Shane discloses a prosthesis essentially consisting of a fluid filled lumen which contributes most of the bulk of the prosthesis (column 5, lines 15-17). In the fluid filled lumen, there is a plurality of thin-walled layers of flexible material. The bulk of the prosthesis, however, consists of a fluid, as illustrated in Figures 1, 4, 5, 6, 7 and 9. A fluid filled lumen is not present in accordance with the implant of the present application. The passage bridging pages 3 and 4 of Applicant's specification clearly states that the volume of the implant of the present invention does not need to be provided with an outer coating layer, and if such coating layer is provided, it is determined by the thin elements having a thickness of 10-200 μm , not by a fluid. The lubricant only fills the capillary gaps between the individual layers and makes only slight contribution to the filling volume.

Thus, the implant according to the claimed invention is distinguishable from Shane in that it consists of a multitude of thin, foldable structural elements having a thickness of 10-200 μm . Also, there is no required amount of fluid, resulting in a structure fundamentally different from that described by Shane. Shane principally refers to a sac-en-sac assembly, which is an entirely different structure.

The Examiner asserts that the layer thickness according to Shane would have to lie in the range as defined by the present invention. However, it is submitted that that the maximum

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thickness of 0.2 mm appears to be impossible according to Shane because the layers are not allowed to fold, as this might cause the entire structure collapsing. Thus, the overall structure of Applicant's implant provides a unique support system for the entire implant.

Neither Wiese nor Scarborough remedy the deficiencies of Shane.

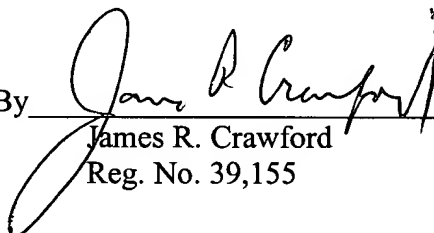
(9) CONCLUSION

All final rejections based on Shane, either alone or in view of Wiese or Scarborough should be reversed and the application should be allowed.

Respectfully requested.

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APPENDIX A- PENDING CLAIMS

1. Implant for the reconstruction of soft tissue, said implant comprising: a plurality of thin pliable structural elements made of a thin sheet of a physiologically compatible plastic having a thickness of 10-200 μm and a surface that is wettable by a fluid lubricant, wherein adjacent structural elements are displaceable one against the other.

2. Implant for the reconstruction of soft tissue, said implant comprising: a plurality of thin pliable structural elements made of a thin sheet of a physiologically compatible plastic having a thickness of 10-200 μm and a surface that is wettable by a fluid lubricant.

5. Implant according to claim 1 wherein the structural elements comprise tubes formed of said thin sheet.

6. Implant according to claim 1, wherein said implant has a hydrophilized surface.

7. Implant according to claim 1 wherein said surface of said thin sheet is hydrophilized and said implant contains an aqueous fluid wetting the hydrophilized surface as the lubricant.

8. Implant according to claim 1, wherein the thin pliable structural element is capable of swelling when contacted with a suitable liquid.

9. Implant according to claim 1 wherein the surface is wetted by said fluid lubricant, and the lubricant is swellable.

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10. Implant according to claim 9, wherein the lubricant is a polysaccharide or glucosaminoglycan.
11. Implant according to claim 1, wherein the surface of each thin pliable structural element includes a hydrophobized surface.
12. Implant according to claim 11, wherein said implant contains fat or oil wetting the hydrophobized surface as the fluid lubricant.
13. Implant according to claim 1, wherein the plastic is a silicone rubber.
14. Implant according to claim 13, wherein the silicone rubber is composed of polydimethylsiloxane.
15. Implant according to claim 1, wherein the plastic is a polysaccharide.
16. Implant according to claim 1, wherein the plastic is cuprophane.
17. Implant according to claim 1, wherein the pliable structural element has a foam structure.
18. Implant according to claim 1, wherein an X-ray contrast medium or a dye is incorporated into the plastic of the structural element.

19. An implant for the reconstruction of soft tissue, said implant comprising:
a plurality of structural elements lying on top of one another to provide a thickness to said implant;

said structural elements being formed of pliable sheet of a physiologically compatible plastic, said sheet having a thickness of 10 to 200 μm ; and

said structural elements having a surface that is adapted to be wetted by a fluid such that, when said surfaces are wetted a sliding movement^{is provided} between said structural elements as the implant is flexed, wherein adjacent structural elements are slideable one against the other, the fluid acting as a lubricant

20. The implant according to claim 19, and
a fluid lubricant contacting said structural elements and providing lubricated sliding movement between said structural elements during flexure of said implant.

21. The implant according to claim 20, and
an outer covering surrounding and enclosing said structural elements.

22. The implant according to claim 20, wherein said structural elements each being a layer of said sheet stacked with the other structural elements to provide a thickness to the implant.